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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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SMITH, GAMBRELL & RUSSELL			BROWN, COURTNEY A	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,992	MEYER ET AL.	
	Examiner	Art Unit	
	COURTNEY BROWN	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 August 2010.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3,5,7,9 and 12-14 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,3,5,7,9 and 12-14 is/are rejected.
 7) Claim(s) 11 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Acknowledgement of Receipt/Status of Claims

This Office Action is in response to the amendment filed August 16, 2010. Claims **1, 3,5,7,9 and 11-14** are pending in the application. Claims 2,4,6,8 and 10 have been cancelled. Claims 1, 3, 5, and 12 have been amended. Claims **1, 3,5,7,9 and 11-14** are being examined for patentability.

Withdrawn Rejections

Applicant's amendments and arguments filed August 16,2010 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn.

The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application. The rejection of claims 1,2,5,7,9 and 12 under 35 U.S.C. 112, second paragraph has been withdrawn in view of Applicant's amendment. The rejection of claims 1-14 under 35 U.S.C. 103(a) as being unpatentable over Kerner et al. (US 2002/0168524 A1) as evidenced by <http://medical dictionary.thefreedictionary.com/silanization> in view of Shimohata et al. (JP 2003292790 A) and Anderson et al. (US Patent

6,521,668 B2) has been withdrawn. This rejection is withdrawn in favor of a new rejection which provides a better motivation to arrive at the claimed invention.

New Rejection(s)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 12 recites the limitation "aggregates of anisotropic primary particles in claim 1. There is insufficient antecedent basis for this limitation in the claim

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3,5,7,9 and 12-14 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Kerner et al. (US 2002/0168524 A1, previously cited) in view of each Mitchnick et al. (US Patent 5,486,631), Korth et al. (US Patent 7,186,768) and Katusic et al. (US Patent 7, 718261).

Applicant's Invention

Applicant claims surface-modified, pyrogenically produced zinc oxides, comprising aggregates and have the following physico-chemical characteristic

data: BET surface areas of $18 \pm 5 \text{ m}^2 / \text{g}$ and C content of 0.5 to 1.0 wt. %

wherein the surface modification includes silanization.

***Determination of the scope and the content of the prior art
(MPEP 2141.01)***

Kerner et al. teach surface-modified, doped, pyrogenically produced oxides such as zinc oxide (see [0005]) surface-modified with one or several organosilane compounds as disclosed in claim 2 of the instant application (see abstract and [0007-0118] of Kerner et al., limitation of instant claim 1). Kerner et al. teach a method of producing the surface-modified, pyrogenically produced oxides doped by aerosol, characterized in that the pyrogenically produced oxides are placed in a suitable mixing container, sprayed under intensive mixing, optionally with water and/or acid at first and subsequently with the surface-modification reagent or a mixture of several surface-modification reagents, optionally re-mixed for 15 to 30 minutes and are subsequently tempered at a temperature of 100 to 400 degrees Celsius for a period of 1 to 6 hours ([0119], limitation of instant claim 3). Further, Kerner et al. teach a production method for surface-modified, pyrogenically produced oxides doped by aerosol wherein the pyrogenically produced oxide starting material is mixed as homogeneously as possible with organohalosilanes under conditions, where oxygen is excluded, followed by a step where the mixture is heated with slight amounts of water vapor and optionally, in a continuous stream of inert gas in a treatment chamber designed as an upright tubular oven at temperatures of 200 to 800 degrees

Celsius, preferably 400 to 600 degrees Celsius. The solid and gaseous reaction products are then separated from each other and, if necessary, the solid products are deacidified again and dried (see [0121], limitation of instant claim 5). Kerner et al. teach that the pyrogenically produced oxides doped by aerosol can be doped pyrogenically produced oxides of metals and/or metalloids in which the base components are oxides of metals and/or metalloids produced pyrogenically by flame hydrolysis wherein the BET surface of the doped oxides is between 5 and 600 m²/g ([0122], limitation of instant claim 1),. Kerner et al. teach that it is possible with the method of their invention to dope all known, pyrogenically produced oxides (e.g., zinc oxide, [0131-0132], limitation of instant claim 1).

Kerner et al. additionally teach the use of the pyrogenically produced, surface-modified and doped oxides as UV blockers in cosmetics ([0145], limitation of instant claims 7 and 9). Kerner et al. teach that it is possible with the method of their invention to dope all known, pyrogenically produced oxides (e.g., zinc oxide) with other metal oxides or metalloid oxides or their mixtures and that the aggregate structure or agglomerate structure of the pyrogenic oxide can be influenced by selecting suitable doping components ([0131-0132]). Kerner et al. additionally teach the use of the pyrogenically produced, surface-modified and doped oxides as UV blockers in cosmetics ([0145]). .

***Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)***

The difference between the invention of the instant application and that of Kerner et al. is that Kerner et al. do not expressly teach a surface-modified zinc oxide that has an average diameter of 50 nm to 300 nm. However, the use of a zinc oxide that has an average diameter within the range of 50 nm to 300 nm was known in the prior art. For example, Mitchnick et al. suggest the use of surface-treated zinc oxide particles having a particle size of 203 nm, column 7, line 5) in cosmetic products (column 1, lines 16-18, limitation of instant claim 12).

A second difference between the invention of the instant application and that of Kerner et al. is that Kerner et al. do not expressly teach a surface-modified zinc oxide having carbon content between 0.1-5 percent. However, the use of a surface-modified zinc oxide having carbon content between 0.1-5 percent was known in the prior art. For example, Korth et al. teach the use of a silane-modified oxidic filler with a carbon content of 0.1 - 25 wt% (column 4, lines 5-9) that can be used in cosmetics (column 15, lines 49-53). Korth et al. also teach that said silane-modified oxidic fillers are selected from a group comprising zinc oxide (see claim 11 of Korth et al., limitation of instant claim 1).

A final difference between the invention of the instant application and that of Kerner et al. is that Kerner et al. do not expressly teach that **a.)** The surface-modified zinc oxide aggregates have a shape factor F (circle) of below 0.5 and **b.)** The surface-modified zinc-oxide powder displays at its surface an oxygen concentration as non-desorbable moisture in the form of Zn-OH and/or Zn-OH₂ units of at least 40. However, the use of zinc-oxide particle with the

aforementioned properties was known in the prior art. For example, Katusic et al. teach the use of zinc oxide aggregates have a shape factor F (circle) of below 0.5 (column 2, lines 38-46) and an oxygen concentration as non-desorbable moisture in the form of Zn-OH and/or Zn-OH₂ units of at least 40 (column 2, lines 47-52, limitations of instant claims 13 and 14) in sunscreen formulations.

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Kerner et al. by using zinc oxide particles with a size of 203 nm, to achieve the predictable result of obtaining a composition suitable to be used as a sunscreen. Kerner et al. and Mitchnick et al. teach that it was known in the art to use zinc oxide particles in cosmetic compositions and Mitchnick et al. teach the use of a particle size that falls within the range of 50 to 300 nm as instantly claimed. Thus, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Further, in view of *In re Kerkhoven*, 205 USPQ 1069 (C.C.P.A. 1980), it is *prima facie* obvious to combine two or more compositions each of which is taught by prior art to be useful for the same

purpose in order to form a third composition that is to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in prior art, thus claims that requires no more than mixing together two conventional cosmetic compositions set forth *prima facie* obvious subject matter.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Kerner et al. and Korth et al. to produce a topical sunscreen composition comprising surface-modified zinc oxides with a carbon content between 0.1-5 percent. Korth et al. teach that silane-modified oxidic fillers **can display** a carbon content of between 0.1 and 25 wt. % and can be used in cosmetic compositions. Thus, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Kerner et al. by using zinc oxide particles with **a.)** The surface-modified zinc oxide aggregates have a shape factor F (circle) of below 0.5 and **b.)** The surface-modified zinc-oxide powder displays at its surface an oxygen concentration as non-desorbable moisture in the form of Zn-OH and/or Zn-OH₂ units of at least 40 to achieve the predictable result of

obtaining a composition suitable to be used as a sunscreen. Kerner et al. and Katusic et al. teach that it was known in the art to use zinc oxide particles in sunscreen compositions. Thus, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Further, in view of *In re Kerkhoven*, 205 USPQ 1069 (C.C.P.A. 1980), it is *prima facie* obvious to combine two or more compositions each of which is taught by prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in prior art, thus claims that requires no more than mixing together two conventional cosmetic compositions set forth *prima facie* obvious subject matter

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Examiner's Response to Applicant's Remarks

Applicant's arguments filed on August 16, 2010 with respect to the 103 rejection of claims 1-14 as being unpatentable over Kerner et al. (US 2002/0168524 A1) as evidenced by <http://medicaldictionary.thefreedictionary.com/silanization> in view of Shimohata et al. (JP 2003292790 A) and Anderson et al. (US Patent 6,521,668 B2) have been fully considered but are moot in view of the new ground of rejection. However, the Examiner has addressed Applicant's arguments since the teachings of Kerner et al. has been used in the instant rejection.

Applicant argues that the combination of ZnO with any one of OC, OMC, PISA or BEMT produces synergistic results in terms of SPF (Sun Protection Factor) values (See pages 28-35). The Experiments compare the SPF values for ZnO alone, the OC, OMC, PISA or BEMT component alone, the combination, and in some cases include with the combination isostearic acid. Applicant presented a table that permits a quick comparison of SPF values. Applicant argues that it is clear from the Table that the SPF values for the combination of zinc oxide and the organic sun screen is more than a sum of the SPF values of the individual components. The Table also includes combinations of zinc oxide, the organic sunscreen and isostearic acid (IA), which have SPF values larger than the combination. Common to all the formulation is surface modified pyrogenically produced zinc oxide having a BET surface area of 18 4- 5 mZ/g.

The Examiner agrees with Applicant's conclusion that the data presented in the arguments filed on April 13, 2010 that the SPF values for the combination of zinc oxide and the organic sun screen is more than a sum of the SPF values of the individual components. However, the results presented in the Table are not material to the instant claims 1,3,5,7 and 12-14 because the claims are drawn to a surface-modified pyrogenically produced zinc oxide powder and not to a sunscreen composition. Furthermore, while claim 9 is drawn to a sunscreen composition, the recited genus of "of dermatologically acceptable carrier" is very broad and the provided evidence is not commensurate in scope with this broadly claimed genus.

Applicant further argues that with the amendments to the claims, the teaching of the art is further distinguished since the claims require a silane surface modifying agent and not a dopant. However, the examiner disagrees with this argument because Kerner et al. teaches the use of silanes for surface modification and not doping. Further, the claims, as written, do not require the absence of a dopant.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Allowable Subject Matter

Claim 11 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 11 is allowable because he data presented in the arguments filed on April 13, 2010 (also see pages 28-35 of the instant specification) show that the SPF values for the combination of zinc oxide and the specific organic sun screens recited in the claim is more than a sum of the SPF values of the individual components.

Conclusion

The claims are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR Only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Courtney Brown, whose telephone number is 571-270-3284. The examiner can normally be reached on Monday-Friday from 8 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Fereydoun Sajjadi can be reached on 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Ileana Popa/

Primary Examiner, Art Unit 1633